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Statement of Rep. Christopher Shays
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More than a decade after U.S. armed forces faced exposure to Saddam's chemical arsenal, and four years after the anthrax attacks here at home, the development of medical countermeasures against unconventional weapons remains an elusive goal. A multitude of federal offices and programs pursue separate, shifting, often competing priorities without disciplined linkage to a strategy to address the most pressing threats.

By one count last year, seventy-five high-level federal officials in seven Cabinet departments were responsible for biodefense policies, program execution or budgets. The Department of Health and Human Services, the Department of Homeland Security, the Department of Defense, the Department of Agriculture, the Department of Commerce, the Department of State and the Environmental Protection Agency all have some responsibility for the nation's defenses against chemical, biological and radiological assaults.

To date, this littered landscape has not been fertile soil for the growth of needed countermeasures against the threats posed by the pathogens, toxins, chemicals and isotopes known to be within the grasp of terrorists. Five years ago, the Defense Science Board saw the need for fifty-seven vaccines, drugs and diagnostics to meet the threat. Today we have just two of those in hand.

The Department of Defense (DOD), specifically the Joint Vaccine Acquisition Program (JVAP), offers a sadly illustrative example of the difficulties plaguing the broader federal effort. A 2004 study by the Institute of Medicine (IOM) found the DOD biodefense program fragmented and often prey to competing priorities. Launched in 1997 with $322 million, the JVAP has spent that much, and more. Yet lists of JVAP "accomplishments" provided to the Subcommittee include just one recently licensed therapeutic, no completed vaccines and two target vaccine programs terminated after significant expenditures.

Without question, countermeasure development is an expensive, technically challenging process that cannot be forced to yield results on an arbitrary timetable. But the current approach lacks cohesiveness and urgency. Those trying to advance medical countermeasures face a torturous labyrinth of federal fiefdoms into which billions disappear. Very few antidotes have yet to emerge.

In October 2001, this Subcommittee held a "field" hearing on the development of medical countermeasures against biological warfare agents. We met across the street, in the Department of Health and Human Services headquarters building, because the Capitol complex was closed for anthrax testing and remediation. We were told aggressive steps were being taken to defend both civilian and military personnel against anthrax, smallpox, botulinum toxin and other likely threats.

But today we find the biodefense pipeline still producing little more than promises of cures to come. Project BioShield represents an essential mechanism to streamline the countermeasure development endgame – acquisition. But it does little to accelerate the glacial process of moving vaccines, drugs and other therapies from basic research to final formulation and licensure. That is a function of leadership, coordination and strict adherence to a threat-based strategy.

We asked our witnesses to describe how greater focus and momentum can be brought to this complex process. They bring world class credentials and unmatched experience to our discussion, and we look forward to their testimony.